



California Regulatory Notice Register

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The *California Regulatory Notice Register* is an official state publication of the Office of Administrative Law containing notices of proposed regulatory actions by state regulatory agencies to adopt, amend or repeal regulations contained in the California Code of Regulations. The effective period of a notice of proposed regulatory action by a state agency in the *California Regulatory Notice Register* shall not exceed one year [Government Code § 11346.4(b)]. It is suggested, therefore, that issues of the *California Regulatory Notice Register* be retained for a minimum of 18 months.

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The back-up contact person is:

Name: Robert Hedrick
Address: 1432 Howe Avenue, Suite 85
Sacramento, California 95825
E-Mail Address: robert_hedrick@dca.ca.gov

Inquiries concerning the substance of the proposed regulations may be directed to Donna Kantner (916) 263-2300, ext. 2308.

Website Access Materials regarding this proposal can be found at www.dbc.ca.gov

TITLE 17. CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

NOTICE OF PROPOSED REGULATION ADOPTION

Deadline for Submission of Written Comment: May 29, 2006 — 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Regulations: Conflict of Interest Rules Applicable to Scientific and Medical Working Groups of the CIRM.

Sections Affected:

The proposed regulations adopt Chapter 1 and sections 100001, 100002, 100003, and 100004 of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Sections 125290.50, subd. (e), 125290.55, 125290.60, 125290.65, 125292.10, subds. (i) and (j), Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in early 2005 with the passage of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the In-

stitute. The ICOC members are public officials, appointed on the basis of their experience earned in California’s leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The goal of the CIRM is to sponsor and facilitate research in regenerative medicine that will advance scientific understanding and result in the development of therapies and treatments for a wide range of devastating diseases. To help in this task, the Act created three working groups, called Grants Review, Facilities, and Medical and Ethical Standards, which draw on outside experts for advice. Each of the working groups has patient advocates, as well as outside experts, among its members.

The goal of two of these groups, Grants Review and Facilities, is to provide expert technical evaluation of applications either for research grants or for research facilities. Neither of these committees is responsible for policy discussions or for funding decisions. In both cases, all policy decisions related to the grants and facilities programs and all final decisions about funding are made by the ICOC in open meeting, either upon recommendation by an ICOC Sub-Committee or by the CIRM staff.

In the case of the third committee, Medical and Ethical Standards, the policy decisions are so important and of such general interest that outside experts to aid the CIRM in formulating and recommending the medical and ethical policies that guide the CIRM’s work. The work of this committee differs from the other two in that it does not consider requests for funding.

Because the working groups are purely advisory, members of the groups are not subject to the conflict of interest disclosure and disqualification laws of the Political Reform Act. (Health and Safety Code § 125290.50, subd. (e).) Nevertheless, the ICOC has taken the unprecedented step of subjecting these advisory bodies to stringent conflict of interest requirements as detailed in the draft regulations. The success of the CIRM research program and its ability to maintain the confidence of the people of California depends critically upon the agency’s ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential. The draft regulations have been developed with invaluable input provided by the public at six different public meetings of the ICOC and Legislative Subcommittee and informed by national and state policies addressing these issues in similar contexts. In many cases the regulations are more stringent than existing provisions in state law governing public officials.

Specifically, the proposed regulations define when a conflict of interest arises for working group members and describe their responsibilities with respect to dis-

closure of financial, professional and personal interests, in addition to rules regarding disqualification from participating in decisions when a conflict of interest arises. The regulations are similar, although not identical, to Government Code provisions in the Political Reform Act governing conflict of interest disclosure and disqualification. In many cases the regulations are more stringent than existing provisions in state law governing public officials. Also, the regulations describe the document-retention requirements of the CIRM and working group staffs for purposes of audit to ensure documented compliance with the regulations.

Technical, Theoretical or Empirical Studies, Reports or Documents:

CIRM relied upon:

- 1) The National Academies — Sciences, Engineering, Institute of Medicine, National Research Council — Policy on Committee Composition and Balance and Conflicts of Interest — May 12, 2003 — including forms, available at: <http://www.nationalacademies.org/doi/index.html>
- 2) The National Institutes of Health policies on Conflicts of Interest — http://www.nih.gov/about/ethics_COI.htm.
- 3) University of California Special Research Programs.
- 4) Public input received at six public meetings conducted by the ICOC and its subcommittees on: April 7, 2005; May 6, 2005; May 23, 2005; June 20, 2005; July 12, 2005; August 5, 2005.

Copies of the documents referenced above in numerals 1 through 3 are available on CIRM's website under the "Regulations" link at www.cirm.ca.gov. These documents are also available at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in numeral 4 are also available on CIRM's website under the "Meetings Transcripts" link.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on May 29, 2006. Comments regarding this proposed action may also be transmitted via e-mail to coi.workinggroups@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than May 15, 2006.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The proposed regulations affect only members of the three working groups that are advisory bodies to the ICOC. As such, the regulations are not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory actions.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed actions will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination

of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

C. Scott Tocher, Interim Legal Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

Backup Contact:

Kate Shreve,
CIRM
(415) 396-9100

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at www.cirm.ca.gov.

GENERAL PUBLIC INTEREST

**OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT**

CALIFORNIA ENVIRONMENTAL PROTECTION
AGENCY

Notice to Interested Parties

April 14, 2006

Announcement of a Public Comment Period

**Public comments on the child-specific Reference
Doses (chRDs) for manganese and
pentachlorophenol for use in assessing health risks
at existing and proposed School Sites**

The Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency is making available for review and comment the final Draft Report "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): PROPOSED CHILD-SPECIFIC REFERENCE DOSES (chRDs) FOR SCHOOL SITE RISK ASSESSMENT—manganese and pentachlorophenol." Health and Safety Code (HSC), Section 901(g) requires OEHHA to evaluate and publish, as appropriate, numerical health guidance values (HGVs) or chRDs for those chemicals that would be encountered at school sites and adversely impact school children. ChRDs for the aforementioned chemicals are being considered at this time.

This final public review and comment period follows the requirements set forth in Health and Safety Code Section 57003 for receiving public input. OEHHA has reviewed comments from an external peer review panel assembled by the Office of the President, University of California, and other interested parties in developing the final draft document. OEHHA requests that comments on this final draft report be delivered to OEHHA by 5:00 p.m. May 15, 2006.

If you would like to receive further information on this announcement or have questions, please contact